III. 510(k) Summary

SUBMITTED BY:
Globus Medical Inc.
303 Schell Lane
Phoenixville, PA 19460
(610) 415-9000 x218
Contact: Kelly J. Baker

SEP - 6 2006

DEVICE NAME:
GATEWAY™ Thoracolumbar Plate System

CLASSIFICATION:
21 CFR §888.3060 Spinal Intervertebral Body Fixation Orthosis
Product Codes KWQ. Regulatory Class II. Panel code 87.

PREDICATE DEVICES:
Globus REVERE™ Stabilization System K061202 (SE date July 20, 2006)
DePuy Profile Anterior Thoracolumbar Plate K973060 (SE date Nov 3, 1997).
Product codes KWQ. Regulatory Class II.

DEVICE DESCRIPTION:
The GATEWAY™ Thoracolumbar Plate System consists of plates of various lengths to be used with polyaxial or monoaxial REVERE™ screws and variable or fixed bone screws. Polyaxial or monoaxial REVERE™ screws attach to the rod portion of the plate and variable or fixed bone screws are inserted through the plate, for fixation of GATEWAY plates to the vertebral bodies of the thoracolumbar spine (T1-L5). REVERE™ locking caps are used to connect polyaxial or monoaxial screws to the rod portion of the plate. Optional staples may be used for additional fixation of polyaxial or monoaxial screws to vertebral bodies. Implants are composed of titanium alloy, as specified in ASTM F136, F1295.

INTENDED USE:
The GATEWAY™ Thoracolumbar Plate System is intended for use in the treatment of thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spine surgery.

PERFORMANCE DATA:
Mechanical testing in accordance with the "Guidance for Industry and FDA Staff, Guidance for Spinal Systems 510(k)s", May 3, 2004 is presented.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The GATEWAY™ Thoracolumbar Plate System implants are similar to the predicate Globus REVERE™ Stabilization System (K061202) and DePuy Profile Anterior Thoracolumbar Plate System (K973060), with respect to technical characteristics, performance, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2006

Globus Medical
% Kelly Baker, PhD
Director, Regulatory and Clinical Affairs
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K062407
Trade/Device Name: GATEWAY™ Thoracolumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 16, 2006
Received: August 17, 2006

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

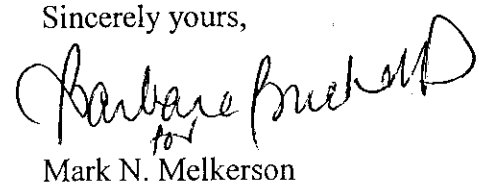
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Indications for Use Statement

510(k) Number: K062407

Device Name: GATEWAY™ Thoracolumbar Plate System

Indications:

The GATEWAY™ Thoracolumbar Plate System is intended for use in the treatment of thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spine surgery.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE ON THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucher

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062407